

EXHIBIT 3

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15
16 UNITED STATES DISTRICT COURT
17 SOUTHERN DISTRICT OF CALIFORNIA

18 IN RE INCRETIN-BASED
19 THERAPIES PRODUCTS LIABILITY
20 LITIGATION

21 As to All Related and Member Cases
22
23
24
25

MDL No. 2452

Magistrate: Mitchell D. Dembin
Judge: Anthony J. Battaglia

**DEFENDANT ELI LILLY AND
COMPANY'S OBJECTIONS
AND RESPONSES TO
PLAINTIFFS' GENERAL
CAUSATION REQUESTS TO
PRODUCE**

1 PROPOUNDING PARTY: Plaintiff

2 RESPONDING PARTY: Defendant Eli Lilly and Company

3 SET NUMBER: General Causation

4 Pursuant to Rule 34 of the Federal Rules of Civil Procedure, defendant
5 Eli Lilly and Company (“Lilly”) hereby responds and objects to the General
6 Causation Requests to Produce propounded by the Plaintiffs’ Steering Committee
7 as follows:

8 **PREFACE**

9 1. Lilly co-promoted Byetta with Amylin Pharmaceuticals, LLC (“Amylin”)
10 pursuant to a collaboration agreement in effect from September 2002 until
11 November 2011. Lilly’s co-promotion of Byetta ended in November 2011, and
12 Lilly has concluded its exenatide-related activities and transitioned all exenatide
13 related activities and responsibilities to Amylin, with minor exceptions not material
14 here in certain other countries pending formal transfer of the Market Authorization
15 in those countries. Unless otherwise stated, Lilly’s responses to these requests to
16 produce are within the date scope of January 1, 2002 through March 31, 2013.

17 2. Amylin and Lilly have to date produced several million DOCUMENTS to
18 members of the Plaintiffs’ Steering Committee (“PSC”). In December 2012,
19 Amylin and Lilly produced 4.5 million pages of DOCUMENTS covering the period
20 before December 28, 2009, including the Byetta IND/NDA, the ADVERSE
21 EVENT reporting database, and custodial DOCUMENTS from the following
22 safety, regulatory, medical, and marketing custodians involved with Byetta:

Amylin

- Diane Beck - Director, Regulatory and Global Safety Operations
- Gary Bloomgren - Senior Director, R&D
- Tom Carpenter - VP, R&D Operations
- Staci Ellis - Director, Regulatory Affairs
- Mark Fineman - Senior Director, R&D Strategic Relations
- Orville Kolterman - Senior VP, R&D
- Dana Lee - Director, Pharmacovigilance
- David Maggs - VP, R&D Strategic Relations,
- Oleg Martynov - Director of Global Safety
- David Parkes - Senior Director, InVivo Pharmacology
- Ruth Patterson - Director of Medical Writing
- Lisa Porter - VP, R&D ExenatideOne
- Denis Roy - Senior Director, Global Pre-Clinical Lead
- Catherine Schnabel - Associate Director, Medical Affairs
- Kika Teudt - Manager, Regulatory Affairs
- Cheryl Watton - Executive Director, Regulatory Affairs and Global Safety
- Dawn Viveash - VP, Regulatory Affairs and Global Safety

Lilly

- Pamela Anderson - Medical Fellow, U.S. Medical Endocrinology
- Dan Braun - Medical Fellow, Global Patient Safety
- Kathryn Broderick - Advisor, Global Regulatory Affairs U.S.
- Jeffrey Ferguson - Medical Fellow, Global Patient Safety
- Drew Fine - Product Brand Director
- John Holcombe - Medical Fellow
- James Malone - Senior Medical Director
- Michael Cobas Meyer - Senior Director, Global Patient Safety
- Rebecca Noel - Research Scientist, Epidemiology
- Donald Therasse - Vice President of Global Patient Safety
- Douglas Wilson - Senior Director of Brand Marketing

On September 27, 2013, Amylin and Lilly provided members of the PSC an updated production consisting of more than five hundred thousand pages of additional DOCUMENTS covering the period from late-2009 to November 2012, including custodial DOCUMENTS from six safety, regulatory and medical custodians involved with Byetta.

3. Lilly objects to Plaintiffs' "Definitions and Instructions" to the extent they purport to impose any obligation on Lilly beyond the obligations imposed by Rule

33 of the Federal Rules of Civil Procedure or to alter the commonly understood meaning of words or phrases.

4. All references to BYETTA within Lilly's responses shall refer to the twice daily injectable form of exenatide, Byetta®, that was first approved by the FDA on April 28, 2005.

5. All references to "Exenatide" (also known as "exendin-4") shall refer to the 39-amino acid synthetic peptide and is the active ingredient in BYETTA.

6. Lilly objects to each request to the extent it seeks information protected by the attorney-client privilege and/or attorney work product doctrine and will withhold such information.

7. Lilly objects to each request to the extent it seeks information protected by HIPAA or other patient confidentiality laws or privileges.

8. It is Lilly's understanding that Plaintiffs' revised requests for production replace their prior requests, that Plaintiffs have withdrawn the prior requests, and that Defendants' responses to the previously served requests are no longer usable in this litigation. If Plaintiffs' dispute this understanding, then Plaintiffs have exceeded the number of permitted requests that they are entitled to serve under the CMO entered on February 23, 2014, and Lilly objects on that basis.

OBJECTIONS AND RESPONSES

REQUEST NO. 1:

The DOCUMENTS identified in YOUR answers to Plaintiffs' General Causation Interrogatories to Defendant Eli Lilly and Company.

RESPONSE:

Lilly has produced or is producing the documents specifically identified, by bates number or other identifier, as responsive in its answers to Plaintiffs' General Causation Interrogatories.

1 **REQUEST NO. 2:**

2 The IND/NDA and any SNDAs for BYETTA in native electronic
3 searchable format as maintained by YOU.

4 **RESPONSE:**

5 Lilly objects to this request as misdirected to it and refers Plaintiffs to
6 Amylin, the regulatory approval holder for Byetta, for the materials sought by this
7 request. By way of further response, Lilly states that the Byetta IND/NDA,
8 covering the period before December 28, 2009, was previously produced to
9 Plaintiffs at BY00000001-435050, and refers Plaintiffs to Amylin regarding
10 supplementation of this production.

11 **REQUEST NO. 3:**

12 All other correspondence, data and other DOCUMENTS that YOU
13 provided to or received from the FDA related to the safety of BYETTA with
14 respect to pancreatitis and/or pancreatic cancer, which are not part of the IND/NDA
15 or any SNDAs for BYETTA.

16 **RESPONSE:**

17 Lilly objects to this request as misdirected to it and refers Plaintiffs to
18 Amylin, the regulatory approval holder for Byetta, for the materials sought by this
19 request. Lilly objects to providing information also in the possession, custody or
20 control of Amylin which may more reasonably be obtained from it. By way of
21 further response, Lilly notes that communications with the FDA, through December
22 28, 2009, were previously produced to Plaintiffs (*see* BY00390802-BY00403814
23 and BY00416354-BY00418067), and refers Plaintiffs to Amylin regarding
24 supplementation of this production.

25
26 **REQUEST NO. 4:**

27 Corporate organization charts that identify the persons with
28 supervisory responsibility over scientific research into the safety of BYETTA and

1 those working at their direction; the persons responsible for determining whether
2 BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer and those
3 working at their direction; the persons in charge of compiling and reporting
4 pancreatitis and/or pancreatic cancer ADVERSE EVENTS for BYETTA and those
5 working at their direction; and the persons in charge of maintaining the source
6 DOCUMENTS for pancreatitis and/or pancreatic cancer ADVERSE EVENTS for
7 BYETTA and those working at their direction.

8 **RESPONSE:**

9 Lilly has previously produced organizational charts responsive to this
10 request and is supplementing its prior production with additional charts, the bates
11 numbers of which will be identified under separate cover. Lilly objects to this
12 request as not seeking information relevant to whether Byetta is capable of causing
13 pancreatic cancer, to the extent it purports to require the creation of charts not
14 already existing, and to the extent it seeks production of charts encompassing more
15 than the individuals whose custodial files are most likely to contain documents
16 within the scope of general causation discovery. Lilly further objects to this request
17 as ambiguous and interprets it as seeking charts of Lilly's Global Patient Safety
18 organization.

19
20 **REQUEST NO. 5:**

21 A complete list of all BYETTA preclinical, nonclinical and/or animal
22 studies performed, completed, designed, planned and/or contemplated, identifying
23 them by name, number or any other designation YOU use to identify them.

24 **RESPONSE:**

25 Lilly objects to this request as improper under Rule 34 in that it
26 purports to require creation of a document not already existing in the ordinary
27 course and as duplicative of Plaintiffs' General Causation Interrogatory No. 2.
28

Lilly refers Plaintiffs to its objections and answer to General Causation Interrogatory No. 2, which are incorporated by reference as if set forth fully here.

REQUEST NO. 6:

For each BYETTA preclinical, nonclinical and/or animal study performed, completed, designed, planned and/or contemplated, produce the following:

- a. The protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench notes, books, computer files and emails; results; reports; and pancreatic specimens (e.g. histology slides, tissue samples, etc.) for that study;
- b. The database(s) where the above information can be located; and
- c. If an independent investigator, contract research organization, or other third party was involved in the study, produce all DOCUMENTS relating to the work performed, including but not limited to contracts and communications between YOU and said independent investigator, contract research organization, or other third party.

RESPONSE:

Lilly refers Plaintiffs to Amylin for information related to preclinical, nonclinical or animal (collectively, “nonclinical”) studies for Byetta. See Lilly’s answer to Plaintiffs’ General Causation Interrogatory No. 2. Lilly further objects to this request as overbroad and unduly burdensome to the extent it seeks documents regarding nonclinical studies not relevant to general causation and to the extent it seeks documents or materials regarding studies (such as slides, samples, lab notebooks, etc.) beyond those contained in the study report and its attachments. The burden and expense of collecting and producing all such requested materials for every study, regardless of relevance, is unreasonable. Lilly also refers Plaintiffs

1 to its production of custodial files, which Plaintiffs are equally able to search as
2 Lilly for emails and other documents discussing these studies.

3 **REQUEST NO. 7:**

4 The standard operating procedures and/or policy and procedures
5 manuals for BYETTA preclinical, nonclinical and animal studies.

6 **RESPONSE:**

7 Lilly refers Plaintiffs to Amylin for information related to preclinical,
8 nonclinical or animal (collectively, “nonclinical”) studies for Byetta. See Lilly’s
9 answer to Plaintiffs’ General Causation Interrogatory No. 2. Lilly further objects to
10 this request as overbroad and unduly burdensome to the extent it seeks documents
11 regarding nonclinical studies not relevant to general causation and to the extent it
12 seeks documents or materials regarding studies (such as slides, samples, lab
13 notebooks, etc.) beyond those contained in the study report and its attachments.
14 The burden and expense of collecting and producing all such requested materials
15 for every study, regardless of relevance, is unreasonable.

16
17 **REQUEST NO. 8:**

18 Every DOCUMENT that addresses the significance of any preclinical,
19 nonclinical and/or animal study in relation to whether BYETTA CAUSES and/or is
20 capable of CAUSING pancreatic cancer.

21 **RESPONSE:**

22 Lilly objects to this request as overbroad, ambiguous, and not
23 reasonably calculated to lead to discovery of evidence competent to prove or
24 disprove general causation. As drafted, this request encompasses every document
25 containing second- or third-hand opinions by any individuals regardless of their
26 expertise or knowledge. Lilly objects to this request to the extent it seeks
27 documents outside Lilly’s possession, custody, or control or that are publicly and
28

1 equally available to Plaintiffs. Lilly also objects to this request to the extent it seeks
2 documents protected by the attorney-client privilege or work product doctrine.

3 Lilly is preparing for production, in accordance with the schedule set
4 by the Court, custodial files collected using search terms agreed upon with
5 Plaintiffs for certain custodians involved in analysis of the safety of Byetta,
6 including Richard Byrd, Ph.D., Jeff Ferguson, M.D., Daniel Braun, M.D., Richard
7 Bump, M.D., Michael Cobas Meyer, M.D., and Steven Knowles, M.D. By way of
8 further response, Plaintiffs also have available numerous analyses contained in
9 Byetta's IND and NDA, and in Periodic Safety Update Reports and Risk
10 Management Plans produced to date, and which are being supplemented by
11 Amylin.

12
13 **REQUEST NO. 9:**

14 The memoranda, reports and other similar DOCUMENTS that
15 describe the nature and intended purpose of any preclinical, nonclinical and/or
16 animal studies involving BYETTA that are not yet started or completed and, to the
17 extent such DOCUMENTS exist, the protocols; data; researcher and/or laboratory
18 technician notebooks, notes, logs, bench notes, books, computer files and emails;
19 results; reports; and pancreatic specimens (e.g. histology slides, tissue samples,
20 etc.) for each such preclinical, nonclinical and/or animal study.

21 **RESPONSE:**

22 Lilly objects to this request as misdirected to it and refers Plaintiffs to
23 Amylin for the documents sought by this request. Lilly's collaboration agreement
24 with Amylin regarding Byetta terminated in November 2011, and Lilly has
25 concluded and transitioned all exenatide related activities and responsibilities to
26 Amylin, with minor exceptions not material here in certain countries pending
27 formal transfer of the Market Authorization. Lilly further objects to this request as
28 not reasonably calculated to lead to discovery of evidence relevant to general

1 causation to the extent it seeks information about ongoing or future studies, which
2 have yet to yield data.

3
4 **REQUEST NO. 10:**

5 A complete list of all BYETTA human studies performed, completed,
6 designed, planned and/or contemplated, identifying them by name, number or any
7 other designation YOU use to identify them.

8 **RESPONSE:**

9 Lilly objects to this request as improper under Rule 34 in that it
10 purports to require creation of a document not already existing in the ordinary
11 course and as duplicative of Plaintiffs' General Causation Interrogatory No. 2.
12 Lilly refers Plaintiffs to its objections and answer to General Causation
13 Interrogatory No. 2, which are incorporated by reference as if set forth fully here.

14
15 **REQUEST NO. 11:**

16 For each BYETTA human study performed, completed, designed,
17 planned and/or contemplated, produce the following:

- 18 a. The protocols; data; researcher and/or laboratory technician
19 notebooks, notes, logs, bench notes, books, computer files and emails; results;
20 reports; and pancreatic specimens (e.g. histology slides, tissue samples, etc.) for
21 that study;
- 22 b. The database(s) where the above information can be located;
- 23 c. All documentation and/or communication regarding sponsorship
24 of the study; and
- 25 d. If an independent investigator, contract research organization, or
26 other third party was involved in the study, produce all DOCUMENTS relating to
27 the work performed, including but not limited to contracts and communications
28

1 between YOU and said independent investigator, contract research organization, or
2 other third party.

3 **RESPONSE:**

4 In response to this request, Lilly refers Plaintiffs to the table of studies
5 provided in its answer to General Causation Interrogatory Nos. 2 and 6, and to the
6 materials associated with each study as identified in that table, which have already
7 been produced to Plaintiffs or are being produced by Lilly and/or Amylin. Lilly
8 also refers Plaintiffs to its production of custodial files, which Plaintiffs are equally
9 able to search as Lilly for emails and other documents discussing these studies.
10 Lilly's collaboration agreement with Amylin terminated in November 2011, and
11 Lilly has concluded its exenatide-related activities and transitioned all exenatide
12 related activities and responsibilities to Amylin, with minor exceptions not material
13 here in certain countries pending formal transfer of the Market Authorization.
14 Lilly, therefore, objects to this request as unduly burdensome and duplicative to the
15 extent it seeks production from Lilly of study materials that may also be obtained
16 from Amylin. Lilly objects to this request as not reasonably calculated to lead to
17 discovery of evidence relevant to general causation to the extent it seeks
18 information about ongoing or future studies, which have yet to yield data. Lilly
19 also objects to this request as overbroad and unduly burdensome to the extent it
20 seeks documents for every study beyond the materials identified in the table
21 provided in response to General Causation Interrogatory Nos. 2 and 6. The burden
22 and expense of collecting and producing all additional requested materials for every
23 study, regardless of relevance, is unnecessary and unreasonable. If after reviewing
24 the study reports Plaintiffs identify specific additional materials regarding specific
25 studies, Lilly will meet and confer with Plaintiffs regarding the additional materials
26 Plaintiffs seek.

1 **REQUEST NO. 12:**

2 The standard operating procedures and/or policy and procedures
3 manuals for BYETTA human studies.

4 **RESPONSE:**

5 Lilly is producing copies of the standard operating procedures from its
6 Medical Quality System listed in Appendix 2 hereto, covering the period from
7 September 2002 through March 31, 2013.

8
9 **REQUEST NO. 13:**

10 Every DOCUMENT that records, analyzes or discusses information
11 about each person YOU are aware of who was a participant in a BYETTA human
12 study and was diagnosed with pancreatitis and/or pancreatic cancer either while still
13 participating in the study or after withdrawing or otherwise being removed from the
14 study.

15 **RESPONSE:**

16 Lilly refers Plaintiffs to its objections and answers to General
17 Causation Interrogatory Nos. 21 and 22 and to the documents identified in its
18 answers to those interrogatories. Lilly further responds that it is preparing for
19 production, in accordance with the schedule set by the Court, custodial files
20 collected using search terms agreed upon with Plaintiffs for certain custodians
21 involved in the analysis of the safety of Byetta, including Richard Byrd, Ph.D., Jeff
22 Ferguson, M.D., Daniel Braun, M.D., Richard Bump, M.D., Michael Cobas Meyer,
23 M.D., and Steven Knowles, M.D., in addition to custodial files already produced.
24 Plaintiffs are equally able as Lilly to search these custodial files for documents
25 sought by this request. Lilly objects to this request to the extent that it includes
26 material protected by the attorney-client privilege and/or attorney work product
27 doctrine.
28

1 **REQUEST NO. 14:**

2 Every DOCUMENT that addresses the significance of any human
3 study in relation to whether BYETTA CAUSES and/or is capable of CAUSING
4 pancreatic cancer.

5 **RESPONSE:**

6 Lilly objects to this request as ambiguous, overbroad, and not
7 reasonably calculated to lead to the discovery of evidence competent to prove or
8 disprove general causation. As drafted, this request encompasses every document
9 containing second- or third-hand opinions by any individuals regardless of their
10 expertise or knowledge. Lilly objects to this request to the extent it seeks
11 documents outside Lilly's possession, custody or control or that are publicly and
12 equally available to Plaintiffs. Lilly also objects to this request to the extent it seeks
13 documents protected by the attorney-client privilege or work product doctrine.

14 Lilly is preparing for production, in accordance with the schedule set
15 by the Court, custodial files collected using search terms agreed upon with
16 Plaintiffs for certain custodians involved in analysis of the safety of Byetta,
17 including Jeff Ferguson, M.D., Daniel Braun, M.D., Richard Bump, M.D., Michael
18 Cobas Meyer, M.D., Steven Knowles, M.D., and James Malone, M.D. By way of
19 further response, Plaintiffs also have available numerous analyses contained in the
20 IND and NDA, and in Periodic Safety Update Reports and Risk Management Plans
21 produced to date, and which are being supplemented by Amylin.

22
23 **REQUEST NO. 15:**

24 The memoranda, reports and other similar DOCUMENTS that
25 describe the nature and intended purpose of any human studies involving BYETTA
26 that are not yet started or completed and, to the extent such DOCUMENTS exist,
27 the study protocols; data; researcher and/or laboratory technician notebooks, notes,
28

logs, bench notes, books, computer files and emails; results; reports; and pancreatic specimens (e.g. histology slides, tissue samples, etc.) for each such human study.

RESPONSE:

Lilly objects to this request as misdirected to it and refers Plaintiffs to Amylin for the documents sought by this request. Lilly's collaboration agreement with Amylin regarding Byetta terminated in November 2011, and Lilly has concluded its exenatide-related activities and transitioned all exenatide related activities and responsibilities to Amylin, with minor exceptions not material here in certain countries pending formal transfer of the Market Authorization. Lilly further objects to this request as not reasonably calculated to lead to discovery of evidence relevant to general causation to the extent it seeks information about ongoing or future studies, which have yet to yield data.

REQUEST NO. 16:

A complete list of all BYETTA observational studies (including, without limitation, claims database studies, cohort studies and other epidemiological studies) performed, completed, designed, planned and/or contemplated, identifying them by name, number or any other designation YOU use to identify them.

RESPONSE:

Lilly objects to this request as improper under Rule 34 in that it purports to require creation of a document not already existing in the ordinary course and as duplicative of Plaintiffs' General Causation Interrogatory No. 2. Lilly refers Plaintiffs to its objections and answer to General Causation Interrogatory No. 2, which are incorporated by reference as if set forth fully here.

1 **REQUEST NO. 17:**

2 For each BYETTA observational study (including, without limitation,
3 claims database studies, cohort studies and other epidemiological studies)
4 performed, completed, designed, planned and/or contemplated, produce the
5 following:

6 a. The protocols; data; researcher and/or laboratory technician
7 notebooks, notes, logs, bench notes, books, computer files and emails; results; and
8 reports for that study;

9 b. The database(s) where the above information can be located;
10 and

11 c. If an independent investigator, contract research organization, or
12 other third party was involved in the study, produce all DOCUMENTS relating to
13 the work performed, including but not limited to contracts and communications
14 between YOU and said independent investigator, contract research organization, or
15 other third party.

16 **RESPONSE:**

17 Lilly objects to the phrase “observational studies” as used in this
18 request as ambiguous and interprets this request as referring to epidemiological
19 studies not involving human subjects. In response to this request, Lilly refers
20 Plaintiffs to the table of studies provided in its answers to General Causation
21 Interrogatory Nos. 2 and 9 and to the materials associated with each study as
22 identified in that table, which have already been produced to Plaintiffs or are being
23 produced by Lilly and/or Amylin. Lilly also refers Plaintiffs to its production of
24 custodial files, which Plaintiffs are equally able to search as Lilly for emails and
25 other documents discussing these studies. Lilly is preparing for production, in
26 accordance with the schedule set by the Court, custodial files, collected using
27 search terms agreed upon with Plaintiffs, for Rebecca Noel and Stephen Motsko,
28

1 both epidemiologists involved in preparation and analysis of epidemiological
2 studies regarding Byetta.

3 Lilly's collaboration agreement with Amylin terminated in
4 November 2011, and Lilly has concluded its exenatide-related activities and
5 transitioned all exenatide related activities and responsibilities to Amylin, with
6 minor exceptions not material here in certain countries pending formal transfer of
7 the Market Authorization. Lilly therefore objects to this request as unduly
8 burdensome and duplicative to the extent it seeks production from Lilly of study
9 materials which may also be obtained from Amylin. Lilly objects to this request as
10 not reasonably calculated to lead to discovery of evidence relevant to general
11 causation to the extent it seeks information about ongoing or future studies, which
12 have yet to yield data. Lilly also objects to this request as overbroad and unduly
13 burdensome to the extent it seeks documents for every study beyond the materials
14 identified in the table provided in response to General Causation Interrogatory Nos.
15 2 and 9. The burden and expense of collecting and producing all additional
16 requested materials for every study, regardless of relevance, is unnecessary and
17 unreasonable. If after reviewing the study reports Plaintiffs identify specific
18 additional materials regarding specific studies, Lilly will meet and confer with
19 Plaintiffs regarding the additional materials Plaintiffs seek.

20
21 **REQUEST NO. 18:**

22 The standard operating procedures and/or policy and procedures
23 manuals for BYETTA observational studies (including, without limitation, claims
24 database studies, cohort studies and other epidemiological studies).

25 **RESPONSE:**

26 Lilly refers Plaintiffs to the individual study reports of epidemiological
27 studies for the methodology followed by the study. By way of further response,
28 Lilly refers Plaintiffs to the Safety Quality System procedures it has produced and

1 is producing (see Appendix 1 hereto) for procedures related to post-marketing
2 surveillance and signal evaluation.

3
4 **REQUEST NO. 19:**

5 Every DOCUMENT that addresses the significance of any
6 observational studies (including, without limitation, claims database studies, cohort
7 studies and other epidemiological studies) in relation to whether BYETTA
8 CAUSES and/or is capable of CAUSING pancreatic cancer.

9 **RESPONSE:**

10 Lilly objects to this request as ambiguous, overbroad and not
11 reasonably calculated to lead to discovery of evidence competent to prove or
12 disprove general causation. As drafted, this request encompasses every document
13 containing any opinions by any individuals regardless of their expertise or
14 knowledge. Lilly objects to this request to the extent it seeks documents outside
15 Lilly's possession, custody or control or that are publicly and equally available to
16 Plaintiffs. Lilly also objects to this request to the extent it seeks documents
17 protected by the attorney-client privilege or work product doctrine.

18 Lilly is preparing for production, in accordance with the schedule set
19 by the Court, custodial files collected using search terms agreed upon with
20 Plaintiffs for certain custodians involved in analysis of the safety of Byetta,
21 including epidemiologists, Stephen Motsko, Ph.D. and Rebecca Noel, Ph.D., and
22 physicians, Jeff Ferguson, M.D., Daniel Braun, M.D., Richard Bump, M.D.,
23 Michael Cobas Meyer, M.D., Steven Knowles, M.D., and James Malone, M.D. By
24 way of further response, Plaintiffs also have available numerous analyses contained
25 in the IND and NDA, and in Periodic Safety Update Reports and Risk Management
26 Plans produced to date, and which are being supplemented by Amylin.

1 **REQUEST NO. 20:**

2 The memoranda, reports and other similar DOCUMENTS that
3 describe the nature and intended purpose of any observational studies (including,
4 without limitation, claims database studies, cohort studies and other
5 epidemiological studies) involving BYETTA that are not yet started or completed
6 and, to the extent such DOCUMENTS exist, the study protocols; data; researcher
7 and/or laboratory technician notebooks, notes, logs, bench notes, books, computer
8 files and emails; results; and reports for each such study.

9 **RESPONSE:**

10 Lilly objects to this request as misdirected to it and refers Plaintiffs to
11 Amylin for the documents sought by this request. Lilly's collaboration agreement
12 with Amylin regarding Byetta terminated in November 2011, and Lilly has
13 concluded its exenatide-related activities and transitioned all exenatide related
14 activities and responsibilities to Amylin, with minor exceptions not material here
15 in certain countries pending formal transfer of the Market Authorization. Lilly
16 further objects to this request as not reasonably calculated to lead to discovery of
17 evidence relevant to general causation to the extent it seeks information about
18 ongoing or future studies, which have yet to yield data.

19
20 **REQUEST NO. 21:**

21 The standard operating procedures and/or policy and procedures
22 manuals for BYETTA studies undertaken to determine, in whole or in part, whether
23 BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer.

24 **RESPONSE:**

25 Lilly refers Plaintiffs to the Safety Quality System and Medical
26 Quality System procedures that it has produced and is producing, which are listed
27 in Appendices 1 and 2 hereto.

1 **REQUEST NO. 22:**

2 The study protocols; data; researcher and/or laboratory technician
3 notebooks, notes, logs, bench notes, books, computer files and emails; results; and
4 reports that were provided to the FDA for each study, test, investigation, evaluation
5 and/or assessment undertaken by YOU for the purpose of determining, in whole or
6 in part, whether BYETTA CAUSES and/or is capable of CAUSING pancreatic
7 cancer.

8 **RESPONSE:**

9 Lilly objects to this request as misdirected to it and refers Plaintiffs to
10 Amylin, the regulatory approval holder for Byetta in the United States, for the
11 materials sought by this request as Lilly does not have current information as to
12 which documents have been provided to the FDA. Lilly's collaboration agreement
13 with Amylin regarding Byetta terminated in November 2011. Lilly has concluded
14 its exenatide-related activities and transitioned all exenatide related activities and
15 responsibilities to Amylin, with minor exceptions not material here in certain other
16 countries pending formal transfer of the Market Authorization in those countries.
17 Lilly objects to providing information also in the possession, custody or control of
18 Amylin which may more reasonably be obtained from it. By way of further
19 response, Lilly refers Plaintiffs to its responses to Request Nos. 2 and 3 above.
20

21 **REQUEST NO. 23:**

22 The study protocols; data; researcher and/or laboratory technician
23 notebooks, notes, logs, bench notes, books, computer files and emails; results; and
24 reports that were not provided to the FDA for each study, test, investigation,
25 evaluation and/or assessment undertaken by YOU for the purpose of determining,
26 in whole or in part, whether BYETTA CAUSES and/or is capable of CAUSING
27 pancreatic cancer.
28

1 **RESPONSE:**

2 Lilly objects to this request as misdirected to it and refers Plaintiffs to
3 Amylin, the regulatory approval holder for Byetta in the United States, for the
4 materials sought by this request as Lilly does not have current information as to
5 which documents have been provided to the FDA. Lilly's collaboration agreement
6 with Amylin regarding Byetta terminated in November 2011. Lilly has concluded
7 its exenatide-related activities and transitioned all exenatide related activities and
8 responsibilities to Amylin, with minor exceptions not material here in certain other
9 countries pending formal transfer of the Market Authorization in those countries.
10 Lilly objects to providing information also in the possession, custody or control of
11 Amylin which may more reasonably be obtained from it. By way of further
12 response, Lilly refers Plaintiffs to its responses to Request Nos. 2 and 3 above.

13 **REQUEST NO. 24:**

14 The study protocols; data; researcher and/or laboratory technician
15 notebooks, notes, logs, bench notes, books, computer files and emails; results; and
16 reports that were provided to the EMA for each study, test, investigation, evaluation
17 and/or assessment undertaken by YOU for the purpose of determining, in whole or
18 in part, whether BYETTA CAUSES and/or is capable of CAUSING pancreatic
19 cancer.

20 **RESPONSE:**

21 Lilly objects to this request as misdirected to it and refers Plaintiffs to
22 Amylin, the regulatory approval holder for Byetta in the European Union, for the
23 materials sought by this request as Lilly does not have current information as to
24 which documents have been provided to the EMA. Lilly's collaboration agreement
25 with Amylin regarding Byetta terminated in November 2011, and EMA Market
26 Authorization for Byetta was transferred from Lilly to Bristol-Myers Squibb and
27 AstraZeneca on March 6, 2013. Lilly has concluded its exenatide-related activities
28 and transitioned all exenatide related activities and responsibilities to Amylin, with

1 minor exceptions not material here in certain other countries pending formal
2 transfer of the Market Authorization in those countries. Lilly objects to providing
3 information also in the possession, custody or control of Amylin which may more
4 reasonably be obtained from it. By way of further response, Lilly refers Plaintiffs
5 to its responses to Request Nos. 2 and 3 above. Lilly objects to discovery related to
6 foreign regulatory issues as not relevant to this litigation, which involves Byetta
7 labeling and use in the United States. However, in light of the unique circumstance
8 in this litigation of EMA and FDA having jointly conducted and published an
9 assessment of pancreatic cancer, Lilly will produce its EMA regulatory files for
10 Byetta and Bydureon for the period in which it was the Market Authorization
11 Holder in the European Union. Lilly maintains its position that submissions and
12 communications with foreign regulatory agencies generally are irrelevant in U.S.
13 product liability litigation.

14
15 **REQUEST NO. 25:**

16 The study protocols; data; researcher and/or laboratory technician
17 notebooks, notes, logs, bench notes, books, computer files and emails; results; and
18 reports that were not provided to the EMA for each study, test, investigation,
19 evaluation and/or assessment undertaken by YOU for the purpose of determining,
20 in whole or in part, whether BYETTA CAUSES and/or is capable of CAUSING
21 pancreatic cancer.

22 **RESPONSE:**

23 Lilly objects to this request as misdirected to it and refers Plaintiffs to
24 Amylin, the regulatory approval holder for Byetta in the European Union, for the
25 materials sought by this request as Lilly does not have current information as to
26 which documents have been provided to the EMA. Lilly's collaboration agreement
27 with Amylin regarding Byetta terminated in November 2011, and EMA Market
28 Authorization for Byetta transferred from Lilly to Bristol-Myers Squibb and

1 AstraZeneca on March 6, 2013. Lilly has concluded its exenatide-related activities
2 and transitioned all exenatide related activities and responsibilities to Amylin, with
3 minor exceptions not material here in certain other countries pending formal
4 transfer of the Market Authorization in those countries. Lilly objects to providing
5 information also in the possession, custody or control of Amylin which may more
6 reasonably be obtained from it. Lilly objects to discovery of foreign regulatory
7 issues as not relevant to this litigation, which involves Byetta labeling and use in
8 the United States. However, in light of the unique circumstance in this litigation of
9 EMA and FDA having jointly conducted and published an assessment of pancreatic
10 cancer, Lilly will produce its EMA regulatory files for Byetta and Bydureon for the
11 period in which it was the Market Authorization Holder in the European Union.
12 Lilly maintains its position that submissions and communications with foreign
13 regulatory agencies generally are irrelevant in U.S. product liability litigation.

14
15 **REQUEST NO. 26:**

16 Every DOCUMENT that addresses the significance of any study, test,
17 investigation, evaluation and/or assessment undertaken by YOU for the purpose of
18 determining, in whole or in part, whether BYETTA CAUSES and/or is capable of
19 CAUSING pancreatic cancer, in relation to whether BYETTA CAUSES and/or is
20 capable of CAUSING pancreatic cancer.

21 **RESPONSE:**

22 This request is duplicative of Request Nos. 8, 14 and 19 above, and
23 Lilly refers Plaintiffs to its objections and responses to those requests, which are
24 incorporated as if set forth fully here.

25
26 **REQUEST NO. 27:**

27 The memoranda, reports and other similar DOCUMENTS that
28 describe the nature and intended purpose of any study, test, investigation,

1 evaluation and/or assessment undertaken by YOU for the purpose of determining,
2 in whole or in part, whether BYETTA CAUSES and/or is capable of CAUSING
3 pancreatic cancer, that is not yet started or completed and, to the extent such
4 DOCUMENTS exist, the study protocols; data; researcher and/or laboratory
5 technician notebooks, notes, logs, bench notes, books, computer files and emails;
6 results; and reports for each such study, test, investigation, evaluation and/or
7 assessment.

8 **RESPONSE:**

9 This request is duplicative of Request Nos. 9, 15 and 20, above, and
10 Lilly refers Plaintiffs to its objections and responses to those requests, which are
11 incorporated as if set forth fully here.

12
13 **REQUEST NO. 28:**

14 The standard operating procedures and/or policy and procedures
15 manuals for all other studies YOU are aware of that bear, in whole or in part, on
16 whether BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer
17 (whether such study, test, investigation, evaluation and/or assessment involves
18 BYETTA, another GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug).

19 **RESPONSE:**

20 This request is duplicative of Request Nos. 7, 12, 18 and 21, above,
21 and Lilly refers Plaintiffs to its objections and responses to those requests, which
22 are incorporated as if set forth fully here. Lilly also objects to this request to the
23 extent it seeks documents related to products other than Byetta, which is the
24 product at issue in Plaintiffs' claims against Lilly. Discovery directed to Lilly
25 regarding other compounds in the GLP-1 or DPP-4 classes is overbroad, unduly
26 burdensome, and not reasonably calculated to lead to admissible evidence.

1 **REQUEST NO. 29:**

2 Every DOCUMENT that addresses the significance of any other study,
3 test, investigation, evaluation and/or assessment YOU are aware of that bears, in
4 whole or in part, on whether BYETTA CAUSES and/or is capable of CAUSING
5 pancreatic cancer (whether such study, test, investigation, evaluation and/or
6 assessment involves BYETTA, another GLP-1 receptor or DPP-4 inhibitor, any
7 other drug, or no drug), in relation to whether BYETTA CAUSES pancreatic
8 cancer.

9 **RESPONSE:**

10 This request is duplicative of Request Nos. 8, 14, 19, and 26 above,
11 and Lilly refers Plaintiffs to its objections and responses to those requests, which
12 are incorporated as if set forth fully here. Lilly also objects to this request to the
13 extent it seeks documents related to products other than Byetta, which is the
14 product at issue in Plaintiffs' claims against Lilly. Discovery directed to Lilly
15 regarding other compounds in the GLP-1 or DPP-4 classes is overbroad, unduly
16 burdensome, and not reasonably calculated to lead to admissible evidence.

17
18 **REQUEST NO. 30:**

19 The memoranda, reports and other similar DOCUMENTS that
20 describe the nature and intended purpose of any other study, test, investigation,
21 evaluation and/or assessment YOU are aware of that bears, in whole or in part, on
22 whether BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer
23 (whether such study, test, investigation, evaluation and/or assessment involves
24 BYETTA, another GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug)
25 that is not yet started or completed and, to the extent such DOCUMENTS exist, the
26 study protocols; data; researcher and/or laboratory technician notebooks, notes,
27 logs, bench notes, books, computer files and emails; results; reports; and pancreatic
28

specimens (e.g., histology slides, tissue samples, etc.) for each such other study, test, investigation, evaluation and/or assessment.

RESPONSE:

This request is duplicative of Request Nos. 9, 15, 20 and 27 above, and Lilly refers Plaintiffs to its objections and responses to those requests, which are incorporated as if set forth fully here. Lilly also objects to this request to the extent it seeks documents related to products other than Byetta, which is the product at issue in Plaintiffs' claims against Lilly. Discovery directed to Lilly regarding other compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and not reasonably calculated to lead to admissible evidence.

REQUEST NO. 31:

The study protocols; data; researcher and/or laboratory technician notebooks, notes, logs, bench notes, books, computer files and emails; results; reports; and pancreatic specimens (e.g., histology slides, tissue samples, etc.) that were provided to the FDA for any other study, test, investigation, evaluation and/or assessment YOU are aware of that bears, in whole or in part, on whether BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer (whether such study, test, investigation, evaluation and/or assessment involves BYETTA, another GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug).

RESPONSE:

Lilly objects to this request as misdirected to it and refers Plaintiffs to Amylin, the regulatory approval holder for Byetta in the United States, for the materials sought by this request as Lilly does not have current information as to which documents have been provided to the FDA. Lilly's collaboration agreement with Amylin regarding Byetta terminated in November 2011. Lilly has concluded its exenatide-related activities and transitioned all exenatide related activities and responsibilities to Amylin, with minor exceptions not material here in certain other

1 countries pending formal transfer of the Market Authorization in those countries.
2 Lilly objects to providing information also in the possession, custody or control of
3 Amylin which may more reasonably be obtained from it. Lilly also objects to this
4 request to the extent it seeks documents related to products other than Byetta, which
5 is the product at issue in Plaintiffs' claims against Lilly. Discovery directed to Lilly
6 regarding other compounds in the GLP-1 or DPP-4 classes is overbroad, unduly
7 burdensome, and not reasonably calculated to lead to admissible evidence. By way
8 of further response, Lilly refers Plaintiffs to its responses to Request Nos. 2 and 3
9 above.

10
11 **REQUEST NO. 32:**

12 The study protocols; data; researcher and/or laboratory technician
13 notebooks, notes, logs, bench notes, books, computer files and emails; results;
14 reports; and pancreatic specimens (e.g., histology slides, tissue samples, etc.) that
15 were not provided to the FDA for any other study, test, investigation, evaluation
16 and/or assessment YOU are aware of that bears, in whole or in part, on whether
17 BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer (whether
18 such study, test, investigation, evaluation and/or assessment involves BYETTA,
19 another GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug).

20 **RESPONSE:**

21 Lilly objects to this request as misdirected to it and refers Plaintiffs to
22 Amylin, the regulatory approval holder for Byetta in the United States, for the
23 materials sought by this request as Lilly does not have current information as to
24 which documents have been provided to the FDA. Lilly's collaboration agreement
25 with Amylin regarding Byetta terminated in November 2011. Lilly has concluded
26 its exenatide-related activities and transitioned all exenatide related activities and
27 responsibilities to Amylin, with minor exceptions not material here in certain other
28 countries pending formal transfer of the Market Authorization in those countries.

1 Lilly objects to providing information also in the possession, custody or control of
2 Amylin which may more reasonably be obtained from it. Lilly also objects to this
3 request to the extent it seeks documents related to products other than Byetta, which
4 is the product at issue in Plaintiffs' claims against Lilly. Discovery directed to Lilly
5 regarding other compounds in the GLP-1 or DPP-4 classes is overbroad, unduly
6 burdensome, and not reasonably calculated to lead to admissible evidence. By way
7 of further response, Lilly refers Plaintiffs to its responses to Request Nos. 2 and 3
8 above.

9
10 **REQUEST NO. 33:**

11 The study protocols; data; researcher and/or laboratory technician
12 notebooks, notes, logs, bench notes, books, computer files and emails; results;
13 reports; and pancreatic specimens (e.g., histology slides, tissue samples, etc.) that
14 were provided to the EMA for any other study, test, investigation, evaluation and/or
15 assessment YOU are aware of that bears, in whole or in part, on whether BYETTA
16 CAUSES and/or is capable of CAUSING pancreatic cancer (whether such study,
17 test, investigation, evaluation and/or assessment involves BYETTA, another GLP-1
18 receptor or DPP-4 inhibitor, any other drug, or no drug).

19 **RESPONSE:**

20 Lilly objects to this request as misdirected to it and refers Plaintiffs to
21 Amylin, the regulatory approval holder for Byetta in the European Union, for the
22 materials sought by this request as Lilly does not have current information as to
23 which documents have been provided to the EMA. Lilly's collaboration agreement
24 with Amylin regarding Byetta terminated in November 2011, and EMA Market
25 Authorization for Byetta transferred from Lilly to Bristol-Myers Squibb and
26 AstraZeneca on March 6, 2013. Lilly has concluded its exenatide-related activities
27 and transitioned all exenatide related activities and responsibilities to Amylin, with
28 minor exceptions not material here in certain other countries pending formal

1 transfer of the Market Authorization in those countries. Lilly objects to providing
2 information also in the possession, custody or control of Amylin which may more
3 reasonably be obtained from it. Lilly objects to this request to the extent it seeks
4 documents related to products other than Byetta, which is the product at issue in
5 Plaintiffs' claims against Lilly. Discovery directed to Lilly regarding other
6 compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and
7 not reasonably calculated to lead to admissible evidence. Lilly also objects to
8 discovery of foreign regulatory issues as not relevant to this litigation, which
9 involves Byetta labeling and use in the United States. However, in light of the
10 unique circumstance in this litigation of EMA and FDA having jointly conducted
11 and published an assessment of pancreatic cancer, Lilly will produce its EMA
12 regulatory files for Byetta and Bydureon for the period in which it was the Market
13 Authorization Holder in the European Union. Lilly maintains its position that
14 submissions and communications with foreign regulatory agencies generally are
15 irrelevant in U.S. product liability litigation.

16
17 **REQUEST NO. 34:**

18 The study protocols; data; researcher and/or laboratory technician
19 notebooks, notes, logs, bench notes, books, computer files and emails; results;
20 reports; and pancreatic specimens (e.g., histology slides, tissue samples, etc.) that
21 were not provided to the EMA for any other study, test, investigation, evaluation
22 and/or assessment YOU are aware of that bears, in whole or in part, on whether
23 BYETTA CAUSES and/or is capable of CAUSING pancreatic cancer (whether
24 such study, test, investigation, evaluation and/or assessment involves BYETTA,
25 another GLP-1 receptor or DPP-4 inhibitor, any other drug, or no drug).

26 **RESPONSE:**

27 Lilly objects to this request as misdirected to it and refers Plaintiffs to
28 Amylin, the regulatory approval holder for Byetta in the European Union, for the

1 materials sought by this request as Lilly does not have current information as to
2 which documents have been provided to the EMA. Lilly's collaboration agreement
3 with Amylin regarding Byetta terminated in November 2011, and EMA Market
4 Authorization for Byetta transferred from Lilly to Bristol-Myers Squibb and
5 AstraZeneca on March 6, 2013. Lilly has concluded its exenatide-related activities
6 and transitioned all exenatide related activities and responsibilities to Amylin, with
7 minor exceptions not material here in certain other countries pending formal
8 transfer of the Market Authorization in those countries. Lilly objects to providing
9 information also in the possession, custody or control of Amylin which may more
10 reasonably be obtained from it. By way of further response, Lilly refers Plaintiffs
11 to its responses to Request Nos. 2 and 3 above. Lilly objects to discovery of
12 foreign regulatory issues as not relevant to this litigation, which involves Byetta
13 labeling and use in the United States. However, in light of the unique circumstance
14 in this litigation of EMA and FDA having jointly conducted and published an
15 assessment of pancreatic cancer, Lilly will produce its EMA regulatory files for
16 Byetta and Bydureon for the period in which it was the Market Authorization
17 Holder in the European Union. Lilly maintains its position that submissions and
18 communications with foreign regulatory agencies generally are irrelevant in U.S.
19 product liability litigation.

20
21 **REQUEST NO. 35:**

22 All emails, letters, reports, memoranda and other written
23 communications YOU have sent to or received from any governmental agency
24 (including, without limitation, the FDA and EMA) or any other entity or person
25 regarding whether BYETTA or any other GLP-1 agonist or DPP-4 inhibitor
26 CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic cancer.
27
28

1 **RESPONSE:**

2 With respect to communications with the FDA and EMA, this request
3 is duplicative of Request Nos. 2, 3, 22, 24, 31 and 33 above, and Lilly refers
4 Plaintiffs to its objections and responses to those requests. To the extent this
5 request seeks “all” correspondence with “any other entity or person,” Lilly objects
6 to this request as overbroad, unduly burdensome, and not reasonably calculated to
7 lead to discovery of competent evidence regarding general causation. The
8 relevance of evidence to general causation does not depend on whether it was
9 communicated to some “other entity or person.” Lilly also objects this request to
10 the extent it seeks documents related to products other than Byetta, which is the
11 product at issue in Plaintiffs’ claims against Lilly. Discovery directed to Lilly
12 regarding other compounds in the GLP-1 or DPP-4 classes is overbroad, unduly
13 burdensome and not reasonably calculated to lead to admissible evidence. Lilly
14 further objects to this request to the extent it includes material protected by the
15 attorney-client privilege and/or attorney work product doctrine. Lilly also objects
16 to this interrogatory as overbroad to the extent it seeks information regarding
17 pancreatitis.

18
19 **REQUEST NO. 36:**

20 If any of YOUR employees, officers, directors, agents, contractors,
21 key opinion leaders, members of speakers’ bureaus, advisory board members, or
22 scientific advisors corresponded with or supplied information or data to the
23 European Medicines Agency (EMA) about or in connection with any assessments
24 of whether BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES
25 and/or is capable of CAUSING pancreatic cancer (including, without limitation, as
26 reflected in the EMA’s 2013 “Assessment report for GLP-1 based therapies” and its
27 2014 “Pancreatic Safety of Incretin-Based Drugs - FDA and EMA Assessment”),
28

1 produce the correspondence, information or data provided to the EMA, and any
2 correspondence or other DOCUMENTS YOU received from the EMA in response.

3 **RESPONSE:**

4 In light of the unique circumstance in this litigation of EMA and FDA
5 having jointly conducted and published an assessment of pancreatic cancer, Lilly
6 will produce its EMA regulatory files for Byetta and Bydureon for the period in
7 which it was the Market Authorization Holder in the European Union. Lilly's
8 collaboration agreement with Amylin regarding Byetta terminated in November
9 2011, and EMA Market Authorization for Byetta transferred from Lilly to Bristol-
10 Myers Squibb and AstraZeneca on March 6, 2013. Lilly maintains its position that
11 submissions and communications with foreign regulatory agencies generally are
12 irrelevant in U.S. product liability litigation and objects to any other discovery of
13 foreign regulatory issues as not relevant to this litigation, which involves Byetta
14 labeling and use in the United States.

15 Lilly also objects to this request as overbroad, unduly burdensome, and
16 not reasonably calculated to lead to admissible evidence in that it seeks documents
17 related to products other than Byetta, which is the only product at issue in
18 Plaintiffs' claims against Lilly. Discovery directed to Lilly regarding other
19 compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and
20 not reasonably calculated to lead to admissible evidence. Lilly also objects to this
21 interrogatory as overbroad to the extent it seeks information regarding pancreatitis.
22 Lilly further objects to this request as overbroad, unreasonably burdensome, and
23 exceeding the scope of Rule 34 to the extent it seeks production from Lilly of
24 communications by third parties such as "contractors, key opinion leaders,
25 members of speakers' bureaus, advisory board members, or scientific advisors."
26
27
28

1 **REQUEST NO. 37:**

2 If any of YOUR employees, officers, directors, agents, contractors,
3 key opinion leaders, members of speakers' bureaus, advisory board members, or
4 scientific advisors corresponded with or supplied information or data to the FDA
5 about or in connection with any assessments of whether BYETTA or any other
6 GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING
7 pancreatic cancer (including, without limitation, as reflected in the FDA's 2014
8 "Pancreatic Safety of Incretin-Based Drugs - FDA and EMA Assessment"),
9 produce the correspondence, information or data, and any correspondence or other
10 DOCUMENTS YOU received from the FDA in response.

11 **RESPONSE:**

12 Lilly objects to this request as misdirected to it and refers Plaintiffs to
13 Amylin, the regulatory approval holder for Byetta in the United States, for the
14 materials sought by this request. By way of further response, Lilly refers Plaintiffs
15 to its responses to Request Nos. 2 and 3 above.

16 Lilly also objects to this request as overbroad, unduly burdensome, and
17 not reasonably calculated to lead to admissible evidence in that it seeks documents
18 related to products other than Byetta, which is the only product at issue in
19 Plaintiffs' claims against Lilly. Discovery directed to Lilly regarding other
20 compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and
21 not reasonably calculated to lead to admissible evidence. Lilly also objects to this
22 interrogatory as overbroad to the extent it seeks information regarding pancreatitis.
23 Lilly further objects to this request as overbroad, unreasonably burdensome, and
24 exceeding the scope of Rule 34 to the extent it seeks production from Lilly of
25 communications by third parties such as "contractors, key opinion leaders,
26 members of speakers' bureaus, advisory board members, or scientific advisors."
27
28

1 **REQUEST NO. 38:**

2 The standard operating procedures and/or policy and procedures
3 manuals for the handling of pancreatitis and pancreatic cancer ADVERSE
4 EVENTS and REPORTABLE EVENTS pertaining to BYETTA.

5 **RESPONSE:**

6 Lilly refers Plaintiffs to the procedures of its Global Patient Safety
7 department it has produced and is producing, which are listed in Appendix 1 hereto
8 and which cover the period prior to March 2013, when Lilly's role in adverse event
9 processing terminated.

10
11 **REQUEST NO. 39:**

12 Produce in electronic format complete copies of all databases used to
13 track, trend, or record information regarding pancreatitis and pancreatic cancer
14 ADVERSE EVENTS that YOU associated with BYETTA. To the extent that
15 YOUR databases incorporate the following information for pancreatitis and
16 pancreatic cancer ADVERSE EVENTS for BYETTA, this request includes:

- 17 a. All DOCUMENTS and information in YOUR possession
18 regarding each ADVERSE EVENT;
- 19 b. Whether the ADVERSE EVENT was in the form of a
20 MedWatch Report, communication from a medical provider or consumer, an
21 ADVERSE EVENT REPORT ("AER") or some other form;
- 22 c. All attempts YOU made to communicate with anyone to gather
23 further information regarding each ADVERSE EVENT;
- 24 d. All communications YOU made or received, including the
25 substance of the communications, the identities of any persons YOU communicated
26 with internally, and the identities of any persons YOU communicated with
27 externally regarding each ADVERSE EVENT;
- 28

1 e. The nature and results of any investigations YOU conducted to
2 determine the CAUSE of each ADVERSE EVENT, and/or the basis of any
3 decisions not to investigate;

4 f. Any experts and/or consultants whom YOU contacted regarding
5 any ADVERSE EVENT;

6 g. YOUR deliberations and decision-making processes used to
7 determine whether each ADVERSE EVENT was or was not a REPORTABLE
8 EVENT;

9 h. Any action YOU took as a result of each ADVERSE EVENT;

10 i. YOUR analysis and conclusions as to the nature, severity and
11 frequency of each ADVERSE EVENT;

12 j. All ADVERSE EVENT report forms, including supplemental
13 reports and related information, that were submitted to the FDA for each
14 ADVERSE EVENT;

15 k. The current status or final disposition of each ADVERSE
16 EVENT; and

17 l. Any reporting rates analysis and/or trending analysis done
18 regarding each ADVERSE EVENT.

19 To the extent that YOUR databases do not incorporate some or all of
20 the information referenced above in subparts a-l, produce the equivalent
21 information by reference to the business records in which YOU store it.

22 **RESPONSE:**

23 Lilly previously produced to Plaintiffs adverse drug reaction reports
24 from the Lilly Safety System in an electronic database format through December
25 28, 2009. *See* LILLY00250453. Lilly is also preparing for production, in
26 accordance with the schedule established by the Court, custodial files collected
27 using search terms agreed upon with Plaintiffs for certain custodians involved in
28 analysis of the adverse drug reaction reports, including Jennifer Brookfield,

1 Pharm.D., Jeff Ferguson, M.D., Daniel Braun, M.D., Richard Bump, M.D., Michael
2 Cobas Meyer, M.D., and Steven Knowles, M.D. In addition, Lilly refers Plaintiffs
3 to the previously produced Periodic Safety Update Reports (PSURs) and Periodic
4 Adverse Drug Experience Reports (PADERs) for Byetta, including Section 3 of the
5 PADERs and Section 6 of the PSURs. Each PSUR also contains appendices,
6 including “Initial and Follow Up Cases and Summary Tabulation of Initial Adverse
7 Drug Events for HCP Not Related and Nonmedically Confirmed Cases” and “Line
8 Listing of Initial and Follow Up Cases and Summary Tabulation of Initial Adverse
9 Drug Reactions for HCP Related Cases.” Previously produced PSURs are located
10 at BY00354544 -BY00354720, BY00361407 - BY00361697, BY00364677 -
11 BY00365031, BY00368455 - BY00368736, BY00372712 - BY00377032,
12 BY00378123 -BY00382063, BY00383891 - BY00383989, BY00387699 -
13 BY00387818, BY00412579 - BY00415581, BY00435059 - BY00437894,
14 BY00437954 -BY00440386, BY00440399 - BY00442435, BY00442447 -
15 BY00444523, BY00444535 - BY00446418, BY00446430 - BY00449028.

16 Lilly’s collaboration agreement with Amylin regarding Byetta
17 terminated in November 2011, and Lilly has concluded its exenatide-related
18 activities and transitioned all exenatide related activities and responsibilities to
19 Amylin, with minor exceptions not material here in certain countries pending
20 formal transfer of the Market Authorization. Lilly objects to this request as unduly
21 burdensome and cumulative to the extent it seeks production from Lilly of
22 documents other than those described in the preceding paragraph and refers
23 Plaintiffs to Amylin for further production in response to this request. Lilly further
24 objects to this request as overbroad, unduly burdensome, and not reasonably
25 calculated to lead to discovery of admissible evidence to the extent it seeks
26 information about adverse events unrelated to the conditions at issue in this
27 litigation, including pancreatitis. Lilly objects to this request to the extent it seeks
28 confidential patient or reporter information, including to the extent it seeks source

1 materials, which require redactions. The burden of preparing and redacting source
2 materials for all adverse drug reactions is unreasonable relative to the minimal
3 relevance and cumulative information contained in such documents. Lilly also
4 objects to this request to the extent it seeks information protected by the attorney-
5 client privilege or work product doctrine.

6
7 **REQUEST NO. 40:**

8 The complete file that YOU established and maintain in response to
9 each individual pancreatitis and pancreatic cancer ADVERSE EVENT for
10 BYETTA (commonly known as “source files,” ADVERSE EVENT report files,
11 backup files, or files containing source documentation related to ADVERSE
12 EVENTS). This request seeks the production of all DOCUMENTS and
13 information contained or discussed in the source files for each ADVERSE EVENT,
14 which should contain most or all of the DOCUMENTS and information described
15 in the preceding request in subparts a-1.

16 **RESPONSE:**

17 This request is duplicative of Request No. 39 above, including subpart
18 39(a). Lilly refers Plaintiffs to its objections and response to Request No. 39,
19 which are incorporated as if set forth fully here.

20
21 **REQUEST NO. 41:**

22 To the extent not already produced in response to the preceding
23 requests, produce all DOCUMENTS for each pancreatitis and pancreatic cancer
24 REPORTABLE EVENT for BYETTA, including the following:

25 a. All DOCUMENTS and information in YOUR possession
26 regarding each REPORTABLE EVENT;
27
28

- 1 b. Whether the REPORTABLE EVENT was in the form of a
2 MedWatch Report, communication from a medical provider or consumer, an
3 ADVERSE EVENT REPORT (“AER”) or some other form;
- 4 c. All attempts YOU made to communicate with anyone to gather
5 further information regarding each REPORTABLE EVENT;
- 6 d. All communications YOU made or received, including the
7 substance of the communications, the identities of any persons YOU communicated
8 with internally, and the identities of any persons YOU communicated with
9 externally regarding each REPORTABLE EVENT;
- 10 e. The nature and results of any investigations YOU conducted to
11 determine the CAUSE of each REPORTABLE EVENT, and/or the basis of any
12 decisions not to investigate;
- 13 f. Any experts and/or consultants whom YOU contacted regarding
14 any REPORTABLE EVENT;
- 15 g. YOUR deliberations and decision-making processes used to
16 determine whether each underlying ADVERSE EVENT was or was not a
17 REPORTABLE EVENT;
- 18 h. Any action YOU took as a result of each REPORTABLE
19 EVENT;
- 20 i. YOUR analysis and conclusions as to the nature, severity and
21 frequency of each REPORTABLE EVENT;
- 22 j. All REPORTABLE EVENT report forms, including
23 supplemental reports and related information, that were submitted to the FDA for
24 each REPORTABLE EVENT;
- 25 k. The current status or final disposition of each REPORTABLE
26 EVENT; and
- 27 l. Any reporting rates analysis and/or trending analysis done
28 regarding each REPORTABLE EVENT.

1 **RESPONSE:**

2 This request is duplicative of Request Nos. 39 and 40 above. Lilly
3 refers Plaintiffs to its objections and response to Request No. 39, which are
4 incorporated as if set forth fully here.

5
6 **REQUEST NO. 42:**

7 All DOCUMENTS that state or discuss any request by the FDA that
8 YOU conduct post-market surveillance of BYETTA with respect to pancreatitis and
9 pancreatic cancer. Include in your response any correspondence, plans, reports, or
10 other DOCUMENTS submitted by YOU to the FDA in response.

11 **RESPONSE:**

12 Lilly refers Plaintiffs to the IND and NDA for Byetta® submitted to
13 the FDA, previously produced to Plaintiffs through December 28, 2009. *See*
14 BY00000001 - BY00449028. Lilly further directs Plaintiffs to the previously
15 produced Byetta Periodic Safety Update Reports at BY00354544 -BY00354720,
16 BY00361407 - BY00361697, BY00364677 - BY00365031, BY00368455 -
17 BY00368736, BY00372712 - BY00377032, BY00378123 - BY00382063,
18 BY00383891 - BY00383989, BY00387699 - BY00387818, BY00412579 -
19 BY00415581, LILLY01449666 - LILLY01451800, BY00437954 - BY00440386,
20 BY00440399 - BY00442435, BY00442447 - BY00444523, BY00444535 -
21 BY00446418, and BY00446430 - BY00449028. Lilly further responds that
22 documents potentially responsive to this request are also contained in custodial files
23 of Lilly employees produced to Plaintiffs. Lilly is preparing for supplemental
24 production, in accordance with the schedule established by the Court, custodial files
25 collected using search terms agreed upon with Plaintiffs for certain custodians
26 involved in analysis of the adverse drug reaction reports, including Jennifer
27 Brookfield, Pharm.D., Jeff Ferguson, M.D., Daniel Braun, M.D., Richard Bump,
28 M.D., Michael Cobas Meyer, M.D., and Steven Knowles, M.D.

1 Lilly's collaboration agreement with Amylin regarding Byetta
2 terminated in November 2011, and Lilly has concluded its exenatide-related
3 activities and transitioned all exenatide related activities and responsibilities to
4 Amylin, with minor exceptions not material here in certain countries pending
5 formal transfer of the Market Authorization. Lilly objects to this request as unduly
6 burdensome and cumulative to the extent it seeks production from Lilly of
7 documents other than those described in the preceding paragraph and refers
8 Plaintiffs to Amylin for further production in response to this request. Lilly also
9 objects to this interrogatory as overbroad to the extent it seeks information
10 regarding pancreatitis. Lilly further objects to this request as not reasonably
11 calculated to lead to discovery of admissible evidence to the extent it seeks
12 documents unrelated to the conditions at issue in this litigation. Lilly also objects
13 to this request to the extent it seeks confidential patient or reporter information and
14 to the extent it seeks information protected by the attorney-client privilege or work
15 product doctrine.

16
17 **REQUEST NO. 43:**

18 All charts, graphs, schematics, reports, memoranda and other similar
19 DOCUMENTS analyzing, summarizing and/or reporting on pancreatitis and/or
20 pancreatic cancer ADVERSE EVENTS for BYETTA, including all such
21 DOCUMENTS that compare BYETTA to any other therapeutic agent(s) for the
22 treatment of type 2 diabetes. To the extent that such DOCUMENTS were prepared
23 in color, they should also be produced in color.

24 **RESPONSE:**

25 Lilly directs Plaintiffs to the previously produced Byetta Periodic
26 Safety Update Reports at BY00354544 -BY00354720, BY00361407 -
27 BY00361697, BY00364677 - BY00365031, BY00368455 - BY00368736,
28 BY00372712 - BY00377032, BY00378123 - BY00382063, BY00383891 -

1 BY00383989, BY00387699 - BY00387818, BY00412579 - BY00415581,
2 LILLY01449666 - LILLY01451800, BY00437954 - BY00440386, BY00440399 -
3 BY00442435, BY00442447 - BY00444523, BY00444535 - BY00446418, and
4 BY00446430 - BY00449028. Lilly further responds that documents potentially
5 responsive to this request are also contained in custodial files of Lilly employees
6 produced to Plaintiffs. Lilly is preparing for supplemental production, in
7 accordance with the schedule established by the Court, custodial files collected
8 using search terms agreed upon with Plaintiffs for certain custodians involved in
9 analysis of the adverse drug reaction reports, including Jennifer Brookfield,
10 Pharm.D., Jeff Ferguson, M.D., Daniel Braun, M.D., Richard Bump, M.D., Michael
11 Cobas Meyer, M.D., and Steven Knowles, M.D.

12 Lilly's collaboration agreement with Amylin regarding Byetta
13 terminated in November 2011, and Lilly has concluded its exenatide-related
14 activities and transitioned all exenatide related activities and responsibilities to
15 Amylin, with minor exceptions not material here in certain countries pending
16 formal transfer of the Market Authorization. Lilly objects to this request as unduly
17 burdensome and cumulative to the extent it seeks production from Lilly of
18 documents other than those described in the preceding paragraph and refers
19 Plaintiffs to Amylin for further production in response to this request. Lilly also
20 objects to this interrogatory as overbroad to the extent it seeks information
21 regarding pancreatitis. Lilly also objects to this request to the extent it includes
22 material protected by the attorney-client privilege and/or attorney work product
23 doctrine.

24
25 **REQUEST NO. 44:**

26 All reports, memoranda and other DOCUMENTS that list and/or
27 explain the criteria YOU use to determine whether any particular pancreatitis and/or
28 pancreatic cancer ADVERSE EVENT is related to the patient's use of BYETTA.

1 **RESPONSE:**

2 Lilly refers Plaintiffs to the procedures of its Global Patient Safety
3 department it has produced and is producing, which are listed in Appendix 1 hereto
4 and which cover the period prior to March 2013, when Lilly's role in adverse event
5 processing terminated. Lilly further responds that documents potentially responsive
6 to this request are also contained in custodial files of Lilly employees produced to
7 Plaintiffs. Lilly is preparing for supplemental production, in accordance with the
8 schedule established by the Court, custodial files collected using search terms
9 agreed upon with Plaintiffs for certain custodians involved in analysis of the
10 adverse drug reaction reports, including Jennifer Brookfield, Pharm.D., Jeff
11 Ferguson, M.D., Daniel Braun, M.D., Richard Bump, M.D., Michael Cobas Meyer,
12 M.D., and Steven Knowles, M.D.

13 Lilly objects to this request to the extent it includes material protected
14 by the attorney-client privilege and/or attorney work product doctrine. Lilly also
15 objects to this interrogatory as overbroad to the extent it seeks information
16 regarding pancreatitis.

17
18 **REQUEST NO. 45:**

19 All medical and scientific literature that YOUR company has
20 identified that relates to the association between BYETTA or any other GLP-1
21 agonist or DPP-4 inhibitor and pancreatitis and/or pancreatic cancer.

22 **RESPONSE:**

23 Lilly objects to this request, which purports to require an evaluation of
24 whether of publicly available literature "relates" to general causation, as unduly
25 burdensome and not reasonably calculated to lead to discovery of any evidence
26 relevant to general causation that is not already equally available to Plaintiffs and
27 their experts. Lilly also objects to this request to the extent it includes material
28 protected by the attorney-client privilege and/or attorney work product doctrine.

1 Lilly refers Plaintiffs to Section 11 of the PBRERs, Section 13 of the
2 PSURs, and Sections 1.13.1.4 and 1.13.2.2 of each Annual Report for references
3 to medical literature relevant to Byetta. Lilly further responds that documents
4 potentially responsive to this request are contained in custodial files of Lilly
5 employees produced to Plaintiffs. Lilly is preparing for supplemental production,
6 in accordance with the schedule established by the Court, custodial files collected
7 using search terms agreed upon with Plaintiffs for certain custodians involved in
8 analysis of the adverse drug reaction reports, including Jennifer Brookfield,
9 Pharm.D., Jeff Ferguson, M.D., Daniel Braun, M.D., Richard Bump, M.D., Michael
10 Cobas Meyer, M.D, and Steven Knowles, M.D.

11 Lilly also objects to this request to the extent it seeks documents
12 related to products other than Byetta, which is the product at issue in Plaintiffs'
13 claims against Lilly. Discovery directed to Lilly regarding other compounds in the
14 GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and not reasonably
15 calculated to lead to admissible evidence. Lilly also objects to this interrogatory as
16 overbroad to the extent it seeks information regarding pancreatitis.

17
18 **REQUEST NO. 46:**

19 All reports, analyses, presentations, memoranda and other
20 DOCUMENTS YOU are aware of that address, in whole or in part, whether
21 BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is
22 capable of CAUSING pancreatitis and/or pancreatic cancer.

23 **RESPONSE:**

24 Lilly refers Plaintiffs to the IND and NDA for Byetta® submitted to
25 the FDA, previously produced to Plaintiffs through December 28, 2009. *See*
26 BY00000001 - BY00449028. Lilly also directs Plaintiffs to the previously
27 produced Byetta Periodic Safety Update Reports at BY00354544 -BY00354720,
28 BY00361407 - BY00361697, BY00364677 - BY00365031, BY00368455 -

1 BY00368736, BY00372712 - BY00377032, BY00378123 - BY00382063,
2 BY00383891 - BY00383989, BY00387699 - BY00387818, BY00412579 -
3 BY00415581, LILLY01449666 - LILLY01451800, BY00437954 - BY00440386,
4 BY00440399 - BY00442435, BY00442447 - BY00444523, BY00444535 -
5 BY00446418, and BY00446430 - BY00449028. Lilly further responds that
6 documents responsive to this request are also contained in custodial files of Lilly
7 employees produced to Plaintiffs. Lilly is preparing for supplemental production,
8 in accordance with the schedule established by the Court, custodial files collected
9 using search terms agreed upon with Plaintiffs for certain custodians involved in
10 analysis of the safety of Byetta, including Jeff Ferguson, M.D., Daniel Braun,
11 M.D., Richard Bump, M.D., Michael Cobas Meyer, M.D., Steven Knowles, M.D.,
12 Richard Byrd, Ph.D., and James Malone, M.D.

13 Lilly's collaboration agreement with Amylin regarding Byetta
14 terminated in November 2011, and Lilly has concluded its exenatide-related
15 activities and transitioned all exenatide related activities and responsibilities to
16 Amylin, with minor exceptions not material here in certain countries pending
17 formal transfer of the Market Authorization. Lilly objects to this request as unduly
18 burdensome and cumulative to the extent it seeks production from Lilly of
19 documents other than those described in the preceding paragraph and refers
20 Plaintiffs to Amylin for further production in response to this request. Lilly also
21 objects to this request to the extent it includes material protected by the attorney-
22 client privilege and/or attorney work product doctrine. Lilly also objects to this
23 interrogatory as overbroad to the extent it seeks information regarding pancreatitis.
24 Lilly also objects to this request to the extent it seeks documents related to products
25 other than Byetta, which is the product at issue in Plaintiffs' claims against Lilly.
26 Discovery directed to Lilly regarding other compounds in the GLP-1 or DPP-4
27 classes is overbroad, unduly burdensome, and not reasonably calculated to lead to
28 admissible evidence. Lilly further objects to this request to the extent it seeks

documents not within Lilly's possession, custody, or control or which are publicly and equally available to Plaintiffs.

REQUEST NO. 47:

To the extent not already produced in response to the preceding requests, all published and unpublished medical and scientific literature, reports, analyses, presentations, memoranda and other DOCUMENTS YOU are aware of that address whether BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES the proliferation of abnormal or dysfunctional beta cells; the proliferation of abnormal or dysfunctional alpha cells; the expansion of pancreatic ductal glands in rats; the formation of dysplastic lesions and chronic pancreatitis in mice; increases in the weight and/or size of the exocrine pancreas; the inhibition of apoptosis of pancreatic ductal cells; and the inhibition of apoptosis of pancreatic islet cells.

RESPONSE:

This request is duplicative of Request Nos. 45 and 46 above, and Lilly refers Plaintiffs to its objections and response to those requests, which are incorporated as if set forth fully here.

REQUEST NO. 48:

To the extent not already produced in response to the preceding requests, all published and unpublished medical and scientific literature, reports, analyses, presentations, memoranda and other DOCUMENTS YOU are aware of that address the mechanism of action of BYETTA or any other GLP-1 agonist or DPP-4 inhibitor.

1 **RESPONSE:**

2 This request is duplicative of Request Nos. 45 and 46 above, and Lilly
3 refers Plaintiffs to its objections and response to those requests, which are
4 incorporated as if set forth fully here.

5
6 **REQUEST NO. 49:**

7 To the extent not already produced in response to the preceding
8 requests, all published and unpublished medical and scientific literature, reports,
9 analyses, presentations, memoranda and other DOCUMENTS YOU are aware of
10 that address the effect that BYETTA or any other GLP-1 agonist or DPP-4 inhibitor
11 has on the pancreas.

12 **RESPONSE:**

13 This request is duplicative of Request Nos. 45 and 46 above, and Lilly
14 refers Plaintiffs to its objections and response to those requests, which are
15 incorporated as if set forth fully here. Lilly further objects to this request as
16 overbroad and not reasonably calculated to lead to discovery of evidence relevant to
17 general causation of pancreatic cancer, to the extent it seeks documents pertaining
18 broadly to any “effect ... on the pancreas” regardless of whether relevant to
19 pancreatic cancer. Lilly also objects to this request to the extent it seeks
20 documents related to products other than Byetta, which is the product at issue in
21 Plaintiffs’ claims against Lilly. Discovery directed to Lilly regarding other
22 compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and
23 not reasonably calculated to lead to admissible evidence.

24
25 **REQUEST NO. 50:**

26 All reports, memoranda and other DOCUMENTS that list and/or
27 explain the criteria YOU use to determine whether BYETTA or any other GLP-1
28

1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis
2 and/or pancreatic cancer.

3 **RESPONSE:**

4 This request is duplicative of Request No. 44 above, and Lilly refers
5 Plaintiffs to its objections and response to that request, which are incorporated as if
6 set forth fully here. Lilly also objects to this request to the extent it seeks
7 documents related to products other than Byetta, which is the product at issue in
8 Plaintiffs' claims against Lilly. Discovery directed to Lilly regarding other
9 compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and
10 not reasonably calculated to lead to admissible evidence. Lilly also objects to this
11 interrogatory as overbroad to the extent it seeks information regarding pancreatitis.
12

13 **REQUEST NO. 51:**

14 All medical and/or scientific literature that YOU have reported to the
15 FDA or any other regulatory authorities that relates to the association between
16 BYETTA and pancreatitis and/or pancreatic cancer, including, but not limited to,
17 all PSURs, PADERS/PAERS, and independent submissions.

18 **RESPONSE:**

19 Lilly objects to this request as misdirected to it and refers Plaintiffs to
20 Amylin, the regulatory approval holder for Byetta in the United States and the
21 European Union, for the materials sought by this request as Lilly does not have
22 current information as to which documents have been provided to the FDA or
23 EMA. Lilly's collaboration agreement with Amylin regarding Byetta terminated in
24 November 2011. Lilly has concluded its exenatide-related activities and
25 transitioned all exenatide related activities and responsibilities to Amylin, with
26 minor exceptions not material here in certain other countries pending formal
27 transfer of the Market Authorization in those countries. Lilly objects to providing
28 information also in the possession, custody or control of Amylin which may more

1 reasonably be obtained from it. By way of further response, Lilly refers Plaintiffs
2 to its responses to Request Nos. 2 and 3 above.

3 Lilly objects to discovery of foreign regulatory issues as not relevant to
4 this litigation, which involves Byetta labeling and use in the United States.
5 However, in light of the unique circumstance in this litigation of EMA and FDA
6 having jointly conducted and published an assessment of pancreatic cancer, Lilly
7 will produce its EMA regulatory files for Byetta and Bydureon for the period in
8 which it was the Market Authorization Holder in the European Union. Lilly
9 maintains its position that submissions and communications with foreign regulatory
10 agencies generally are irrelevant in U.S. product liability litigation. Lilly also
11 objects to this interrogatory as overbroad to the extent it seeks information
12 regarding pancreatitis.

13
14 **REQUEST NO. 52:**

15 To the extent not already produced in response to the preceding
16 requests, produce all communications, analyses, expert analyses, safety board
17 analyses, independent analyses, and/or meta-analyses that pertain to, reference, or
18 in any way discuss any of the medical and scientific literature and/or the preclinical,
19 nonclinical, animal, human, observational and/or other studies referred to above
20 with respect to whether BYETTA or any other GLP-1 agonist or DPP-4 inhibitor
21 CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic cancer.

22 **RESPONSE:**

23 This request is duplicative of Request Nos. 45 and 46 above, and Lilly
24 refers Plaintiffs to its objections and response to those requests, which are
25 incorporated as if set forth fully here.
26
27
28

1 **REQUEST NO. 53:**

2 All communications YOU have had with the author(s) of the medical
3 and/or scientific literature referenced above with respect to whether BYETTA or
4 any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of
5 CAUSING pancreatic cancer.

6 **RESPONSE:**

7 This request is duplicative of Request Nos. 45 and 46 above, and Lilly
8 refers Plaintiffs to its objections and response to those requests, which are
9 incorporated as if set forth fully here. Lilly also objects to this request as
10 ambiguous in that it does not define what is meant by “the medical and/or scientific
11 literature referenced above.” Lilly further objects to this request for “all”
12 communications with unnamed authors as overbroad, unduly burdensome and not
13 reasonably calculated to lead to discovery of competent evidence regarding general
14 causation. The relevance of evidence to general causation does not depend on who
15 it was communicated with.

16
17 **REQUEST NO. 54:**

18 All emails, letters, reports, memoranda and other written
19 communications YOU have had internally regarding whether BYETTA or any
20 other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING
21 pancreatic cancer.

22 **RESPONSE:**

23 This request is duplicative of Request Nos. 45 and 46 above, and Lilly
24 refers Plaintiffs to its objections and response to those requests, which are
25 incorporated as if set forth fully here.

1 **REQUEST NO. 55:**

2 If YOU have made and/or requested label changes in the United States
3 or elsewhere to add or strengthen warnings about the risks of pancreatitis and/or
4 pancreatic cancer associated with BYETTA at any time since YOU began to market
5 BYETTA, provide all DOCUMENTS, including emails, letters, reports,
6 memoranda and other written communications, that YOU have sent to or received
7 from the FDA and/or any applicable foreign country's regulatory authority in
8 connection with each label change and/or request. This request to produce
9 includes, without limitation, any PAS or CBE submitted by YOU to the FDA, and
10 any response YOU have received from the FDA.

11 **RESPONSE:**

12 Lilly has not made or requested label changes "to add or strengthen
13 warnings" regarding the alleged risk of pancreatic cancer. Lilly objects to this
14 request as not relevant to general causation of pancreatic cancer to the extent it
15 seeks documents regarding labeling for pancreatitis. Lilly also objects to discovery
16 of foreign labeling as not relevant to this litigation, which involves Byetta labeling
17 and use in the United States.

18
19 **REQUEST NO. 56:**

20 All emails, letters, reports, memoranda and other written
21 communications to or from any source discussing or referring to physician
22 monitoring and/or testing for pancreatitis and/or pancreatic cancer associated with
23 the use of BYETTA.

24 **RESPONSE:**

25 Lilly objects to this request as unintelligible. To the extent the request
26 seeks communications with "any source," it is also not reasonably calculated to
27 discovery of evidence competent to prove or disprove general causation.

28

1 **REQUEST NO. 57:**

2 The meeting minutes and any summaries of meeting minutes for each
3 internal meeting at which YOU discussed whether BYETTA or any other GLP-1
4 agonist DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis
5 and/or pancreatic cancer.

6 **RESPONSE:**

7 This request is duplicative of Request No. 46 above, and Lilly refers
8 Plaintiffs to its objections and response to that request, which are incorporated as if
9 set forth fully here. Lilly further objects to this request as overbroad, unduly
10 burdensome, and not reasonably calculated to lead to discovery of competent
11 evidence regarding general causation. As drafted, this request encompasses every
12 document reflecting opinions by any individuals regardless of their expertise or
13 knowledge. Lilly also objects to this interrogatory as overbroad to the extent it
14 seeks information regarding pancreatitis.

15
16 **REQUEST NO. 58:**

17 All notes, recordings, handouts, materials and presentations YOU or
18 YOUR employees are aware of that were made or obtained in connection with any
19 meeting, conference or other event, internal or external, at which the subject of
20 whether BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or
21 is capable of CAUSING pancreatitis and/or pancreatic cancer was discussed.

22 **RESPONSE:**

23 This request is duplicative of Request No. 46 above, and Lilly refers
24 Plaintiffs to its objections and response to that request, which are incorporated as if
25 set forth fully here. Lilly further objects to this request as overbroad, unduly
26 burdensome, and not reasonably calculated to lead to discovery of competent
27 evidence regarding general causation. As drafted, this request encompasses every
28

1 document reflecting opinions by any individuals regardless of their expertise or
2 knowledge.

3
4 **REQUEST NO. 59:**

5 If the sale of BYETTA has ever been prohibited due to concerns that it
6 may CAUSE pancreatitis and/or pancreatic cancer, produce all emails, letters,
7 reports, memoranda and other written communications received by YOU
8 addressing or discussing those concerns, and all emails, letters, reports, memoranda
9 and other written communications prepared by YOU (whether sent or not sent)
10 addressing or discussing those concerns.

11 **RESPONSE:**

12 Not applicable. The sale of Byetta has not been prohibited since it was
13 initially approved by the FDA as safe and effective.

14
15 **REQUEST NO. 60:**

16 If any of YOUR employees, officers, directors, agents, contractors,
17 key opinion leaders, members of speakers' bureaus, advisory board members, or
18 scientific advisors have corresponded with or supplied information or data to any
19 scientific journal regarding whether BYETTA or any other GLP-1 agonist or DPP-
20 4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic
21 cancer, produce the correspondence, information and/or data.

22 **RESPONSE:**

23 Lilly objects to this request as ambiguous, overbroad, and not
24 reasonably calculated to lead to discovery of evidence relevant to prove or disprove
25 general causation. The relevance or competence of evidence to prove or disprove
26 general causation is not dependent on whom it was communicated to. To the extent
27 this request seeks evidence that is relevant to prove or disprove general causation, it
28 is duplicative of Plaintiffs' other requests that seek such evidence more directly.

1 Lilly also objects to this request as overbroad, unduly burdensome, and not
2 reasonably calculated to lead to admissible evidence in that it seeks documents
3 related to products other than Byetta, which is the only product at issue in
4 Plaintiffs' claims against Lilly. Discovery directed to Lilly regarding other
5 compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and
6 not reasonably calculated to lead to admissible evidence. Lilly also objects to this
7 interrogatory as overbroad to the extent it seeks information regarding pancreatitis.
8 Lilly further objects to this request as overbroad, unreasonably burdensome, and
9 exceeding the scope of Rule 34 to the extent it seeks production from Lilly of
10 communications by third parties such as "contractors, key opinion leaders,
11 members of speakers' bureaus, advisory board members, or scientific advisors."

12
13 **REQUEST NO. 61:**

14 If any of YOUR employees, officers, directors, agents, contractors,
15 key opinion leaders, members of speakers' bureaus, advisory board members, or
16 scientific advisors have submitted a manuscript, case report, article described as an
17 "advertisement," opinion piece or topic to any scientific journal regarding whether
18 BYETTA or any other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is
19 capable of CAUSING pancreatitis and/or pancreatic cancer, produce the material
20 submitted.

21 **RESPONSE:**

22 Lilly objects to this request as ambiguous, overbroad, and not
23 reasonably calculated to lead to discovery of evidence relevant to prove or disprove
24 general causation. The relevance or competence of evidence to prove or disprove
25 general causation is not dependent on whom it was communicated to. To the extent
26 this request seeks evidence that is relevant to prove or disprove general causation, it
27 is duplicative of Plaintiffs' other requests that seek such evidence more directly.
28 Lilly also objects to this request as overbroad, unduly burdensome, and not

1 reasonably calculated to lead to admissible evidence in that it seeks documents
2 related to products other than Byetta, which is the only product at issue in
3 Plaintiffs' claims against Lilly. Discovery directed to Lilly regarding other
4 compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and
5 not reasonably calculated to lead to admissible evidence. Lilly also objects to this
6 interrogatory as overbroad to the extent it seeks information regarding pancreatitis.
7 Lilly further objects to this request as overbroad, unreasonably burdensome, and
8 exceeding the scope of Rule 34 to the extent it seeks production from Lilly of
9 communications by third parties such as "contractors, key opinion leaders,
10 members of speakers' bureaus, advisory board members, or scientific advisors."

11
12 **REQUEST NO. 62:**

13 If any of YOUR employees, officers, directors, agents, contractors,
14 key opinion leaders, members of speakers' bureaus, advisory board members, or
15 scientific advisors have participated in or supplied information or data to any expert
16 meeting, panel or committee investigating or reviewing whether BYETTA or any
17 other GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING
18 pancreatitis and/or pancreatic cancer, produce the correspondence, data and other
19 DOCUMENTS supplied to, received from, or created by such meeting(s), panel(s)
20 or committee proceedings.

21 **RESPONSE:**

22 Lilly objects to this request as ambiguous, overbroad, and not
23 reasonably calculated to lead to discovery of evidence relevant to prove or disprove
24 general causation. The relevance or competence of evidence to prove or disprove
25 general causation is not dependent on whom it was communicated to. To the extent
26 this request seeks evidence that is relevant to prove or disprove general causation, it
27 is duplicative of Plaintiffs' other requests that seek such evidence more directly.
28 Lilly also objects to this request as overbroad, unduly burdensome, and not

1 reasonably calculated to lead to admissible evidence in that it seeks documents
2 related to products other than Byetta, which is the only product at issue in
3 Plaintiffs' claims against Lilly. Discovery directed to Lilly regarding other
4 compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and
5 not reasonably calculated to lead to admissible evidence. Lilly also objects to this
6 interrogatory as overbroad to the extent it seeks information regarding pancreatitis.
7 Lilly further objects to this request as overbroad, unreasonably burdensome, and
8 exceeding the scope of Rule 34 to the extent it seeks production from Lilly of
9 communications by third parties such as "contractors, key opinion leaders,
10 members of speakers' bureaus, advisory board members, or scientific advisors."

11
12 **REQUEST NO. 63:**

13 If any of YOUR employees, officers, directors, agents, contractors,
14 key opinion leaders, members of speakers' bureaus, advisory board members, or
15 scientific advisors corresponded with or supplied information or data to any
16 authors, medical journals, scientific journals, any other publications, any diabetes
17 research or research-funding organizations or persons affiliated with them, any
18 scientific advisors, or any consultants about Dr. Susan Bonner-Weir, Dr. Alexandra
19 E. Butler, Dr. Peter C. Butler, Dr. David D. Dore, Dr. Daniel J. Drucker,
20 Dr. Michael Elashoff, Dr. Robert Elashoff, Dr. Edwin Gale, Dr. Rajesh Garg,
21 Dr. Belinda Gier, Dr. Fred Gorlick, Dr. Steven Kami, Dr. Jacqueline Koehler,
22 Dr. Aleksey V. Matveyenko, Dr. Robert Ratner, Dr. Sonal Singh, or Dr. Jay S.
23 Skyler, and/or about any of the work they have done or authored regarding incretin
24 medications, produce the correspondence, information and/or data.

25 **RESPONSE:**

26 Lilly objects to this request as ambiguous, overbroad, and not
27 reasonably calculated to lead to discovery of evidence relevant to prove or disprove
28 general causation. The relevance or competence of evidence to prove or disprove

1 general causation is not dependent on whom it was communicated to. To the extent
2 this request seeks evidence that is relevant to prove or disprove general causation, it
3 is duplicative of Plaintiffs' other requests that seek such evidence more directly.
4 Lilly also objects to this request as overbroad, unduly burdensome, and not
5 reasonably calculated to lead to admissible evidence in that it seeks documents
6 related to products other than Byetta, which is the only product at issue in
7 Plaintiffs' claims against Lilly. Discovery directed to Lilly regarding other
8 compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and
9 not reasonably calculated to lead to admissible evidence. Lilly also objects to this
10 interrogatory as overbroad to the extent it seeks information regarding pancreatitis.
11 Lilly further objects to this request as overbroad, unreasonably burdensome, and
12 exceeding the scope of Rule 34 to the extent it seeks production from Lilly of
13 communications by third parties such as "contractors, key opinion leaders,
14 members of speakers' bureaus, advisory board members, or scientific advisors."

15
16 **REQUEST NO. 64:**

17 To the extent not already produced in response to the preceding
18 requests, all emails, letters, reports, memoranda and other written communications
19 with authors, medical journals, scientific journals, any other publications, any
20 diabetes research or research-funding organizations or persons affiliated with them,
21 any scientific advisors, or any consultants about whether BYETTA or any other
22 GLP-1 agonist or DPP-4 inhibitor CAUSES and/or is capable of CAUSING
23 pancreatitis and/or pancreatic cancer.

24 **RESPONSE:**

25 Lilly objects to this request as ambiguous, overbroad, and not
26 reasonably calculated to lead to discovery of evidence competent to prove or
27 disprove general causation. The relevance or competence of evidence to prove or
28 disprove general causation is not dependent on whom it was communicated to. To

1 the extent this request seeks evidence that is relevant to prove or disprove general
2 causation, it is duplicative of Plaintiffs' other requests that seek such evidence more
3 directly. Lilly also objects to this request as overbroad, unduly burdensome, and
4 not reasonably calculated to lead to admissible evidence in that it seeks documents
5 related to products other than Byetta, which is the only product at issue in
6 Plaintiffs' claims against Lilly. Discovery directed to Lilly regarding other
7 compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and
8 not reasonably calculated to lead to admissible evidence. Lilly also objects to this
9 interrogatory as overbroad to the extent it seeks information regarding pancreatitis.
10 Lilly further objects to this request as overbroad, unreasonably burdensome, and
11 exceeding the scope of Rule 34 to the extent it seeks production from Lilly of
12 communications by third parties such as "contractors, key opinion leaders,
13 members of speakers' bureaus, advisory board members, or scientific advisors."

14
15 **REQUEST NO. 65:**

16 All DOCUMENTS that constitute or discuss compensation, honoraria,
17 grants, scholarships or gifts, whether offered or actually paid, to individuals or
18 institutions for work (including, without limitation, work done on preclinical
19 studies, nonclinical studies, animal studies, human studies, other research, or the
20 authorship of articles) concerning whether BYETTA or any other GLP-1 agonist or
21 DPP-4 inhibitor CAUSES and/or is capable of CAUSING pancreatitis and/or
22 pancreatic cancer. Include in YOUR response, without limitation, all such
23 DOCUMENTS pertaining to Dr. Susan Bonner-Weir, Dr. David D. Dore,
24 Dr. Daniel J. Drucker, Dr. Rajesh Garg, Dr. Fred Gorlick, Dr. Steven Kahn,
25 Dr. Jacqueline Koehler, Dr. Robert Ratner, Dr. Jay S. Skyler, and/or the companies
26 and/or organizations that employ them.

1 **RESPONSE:**

2 Lilly objects to this request as ambiguous, overbroad, and not
3 reasonably calculated to lead to discovery of evidence competent to prove or
4 disprove general causation. The financial information sought by this request has no
5 tendency to prove or disprove the scientific fact of whether Byetta is capable of
6 causing pancreatic cancer. Lilly also objects to this request as overbroad, unduly
7 burdensome, and not reasonably calculated to lead to admissible evidence in that it
8 seeks documents related to products other than Byetta, which is the only product at
9 issue in Plaintiffs' claims against Lilly. Discovery directed to Lilly regarding other
10 compounds in the GLP-1 or DPP-4 classes is overbroad, unduly burdensome, and
11 not reasonably calculated to lead to admissible evidence. Lilly also objects to this
12 interrogatory as overbroad to the extent it seeks information regarding pancreatitis.
13 Lilly further objects to this request as overbroad, unreasonably burdensome, and
14 exceeding the scope of Rule 34 to the extent it seeks production from Lilly of
15 communications by third parties such as "contractors, key opinion leaders,
16 members of speakers' bureaus, advisory board members, or scientific advisors."

17
18 **REQUEST NO. 66:**

19 All of YOUR DOCUMENT retention, destruction and archiving
20 policies that apply to BYETTA preclinical, nonclinical, animal, human and/or
21 observational studies; other studies addressing, in whole or in part, whether
22 BYETTA CAUSES and/or is capable of CAUSING pancreatitis and/or pancreatic
23 cancer; BYETTA ADVERSE EVENTS; and any other DOCUMENTS addressing
24 whether BYETTA CAUSES and/or is capable of CAUSING pancreatitis and/or
25 pancreatic cancer.

26 **RESPONSE:**

27 Lilly objects to this request as overbroad and not reasonably calculated
28 to lead to discovery of evidence competent to prove or disprove general causation.

1 Record retention policies are unrelated to the issue of general causation. Lilly also
2 objects to this request to the extent it includes material protected by the attorney-
3 client privilege and/or attorney work product doctrine.

4
5 **REQUEST NO. 67:**

6 To the extent that YOU have withheld any DOCUMENTS responsive
7 to any of these requests under any claim of privilege, produce a privilege log as
8 required by Fed. R. Civ. P. 26.

9 **RESPONSE:**

10 Lilly has provided privilege logs for the productions it has made to
11 date and will provide privilege logs for future productions, as well. However, Lilly
12 notes that Plaintiffs' failure to respond to Defendants' proposed stipulation
13 regarding the form and content of privilege logs is delaying Defendants' ability to
14 begin preparation of privilege logs for productions that are currently in progress.

1 DATED: May 9, 2014

PEPPER HAMILTON LLP

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4 

5 By:

6 Nina M. Gussack
7 Kenneth J. King
8 Allan A. Thoen
9 Attorneys for Defendant
10 Eli Lilly and Company
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I am a resident of or employed in the county where the service described below occurred. My business address is 3000 Two Logan Square, Philadelphia, PA 19103. I am familiar with this firm's practice for collection and processing of correspondence for mailing with the United States Postal service. In the ordinary course of business, correspondence collected from me would be processed on the same day, with postage thereon fully prepaid and placed for deposit that day with the United States Postal Service.

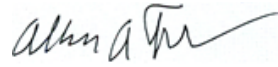
Defendant Eli Lilly and Company's Objections and Responses to Plaintiffs' General Causation Requests to Produce

by putting a true and correct copy thereof in a sealed envelope, with postage fully prepaid, and placing the envelope for collection and mailing today with the United States Postal Service in accordance with the firm's ordinary business practice, and/or by electronic mail, addressed as follows:

Ryan L. Thompson
Watts Guerra LLP
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San Antonio, TX 78240
rthompson@wattsguerra.com
Served by Email

Tor A. Hoerman
Torhoerman Law LLC
101 W. Vandalia Street, Suite 350
Edwardsville, IL 62025
thoerman@torhoermanlaw.com
Served by Email

1 I hereby certify that a copy of the above and foregoing has been mailed and/or sent
2 by electronic mail to the following counsel of record for all of the actions that will
3 be affected on May 9, 2014.

4 

5 _____
6 Allan A. Thoen
7 Attorney for Defendant
8 Eli Lilly and Company
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